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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,924	05/30/2001	Blake J. Roessler	UM-06191	7554

7590 09/28/2005

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/867,924

Applicant(s)

ROESSLER ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-64 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges receipt of request for reconsideration, remarks, declaration under 37 CFR 1.132, request for extension of time, all filed 07/13/05 and change of address filed 01/13/05.

Claim Rejections - 35 USC § 102

1. The rejection of claims 1-15, 25-29, 32-45 and 60-64 under 35 U.S.C. 102(a) as being anticipated by Bielinska et al. ("Applications of membrane-based dendrimer/DNA complexes for solid phase transfection in vitro and in vivo," *Biomaterials*, 21 (2000) 877-887, published May 2000 and cited by applicants on Form PTO-1449) is withdrawn in light of the 132 declaration by Blake J. Roessler for and on behalf of co-inventors Anna U. Bielinska and James Baker and the declarant, Blake J. Roessler where it is stated that the other co-authors of the research publication worked the supervision of the declarant. The declaration does not identify these co-authors as students or research fellows. However, *in re Katz* appears to apply here.

Claim Rejections - 35 USC § 103

2. The rejection of claims 16-24, 30, 31 and 46-59 under 35 U.S.C. 103(a) as being unpatentable over Bielinska et al. ("Applications of membrane-based dendrimer/DNA complexes for solid phase transfection in vitro and in vivo," *Biomaterials*, 21 (2000) 877-887, published May 2000 and cited by applicants on Form PTO-1449) and Shea et al. (WO 99/58656) is withdrawn in light of the 132 declaration by Blake J. Roessler for and on behalf of co-inventors Anna U. Bielinska and James Baker and the declarant, Blake J. Roessler where it is stated that the other co-authors of the research publication worked the supervision of the declarant. The declaration does not identify these co-authors as students or research fellows. However, *in re*

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Katz appears to apply here. The rejection cannot be sustained once Bielinska is not prior art in view of the publication being applicants' (namely Blake J. Roessler, Anna U. Bielinska and James Baker) own work.

However, upon further consideration, the claimed invention is directed to subject matter that places a huge burden on the examiner to conduct a reasonable search of all the species claimed. Therefore, it is examiner's position that a restriction and election is proper. The restriction/election is provided below.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-24, drawn to composition comprising at least one dendrimer and biological agent, classified in class 424, subclass 426.
 - II. Claims 25-58, drawn to method of contacting tissue with a dendrimer containing composition, classified in class 530, subclass 350.
 - III. Claims 60-64, drawn to method for transfecting a tissue by contacting the tissue with a composition, classified in class 435, subclass 455.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process claimed can be practiced with another materially different product.

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5. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case process claimed can be practiced with another materially different product.
6. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are method for transfecting a tissue and the method for contacting a tissue is not necessarily to transfect the tissue.
7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
9. This application contains claims directed to the following patentably distinct species of the claimed invention: The biological agent is varied and different. The dendrimer is bioerodible or biocompatible and a biocompatible dendrimer may not necessarily be bioerodible depending on the polymer.

Therefore, if applicants elect Group I, applicants must further elect:

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- i) a biocompatible or bioerodible membrane (that is elect collagen or PLGA to go with either ii)a or ii)b) and
- ii) a specific biological agent from
 - a) nucleic acid
 - b) protein

Similarly, if applicants elect a), applicants must elect DNA gene that encodes protein that promotes wound healing or DNA gene that encodes protein that promotes tissue vascularization.

And, if applicants elect b) applicants must elect protein that promotes wound healing or a protein that promotes tissue vascularization that is growth factor.

If applicants elect Group II, applicants must further elect:

- iii) a biocompatible or bioerodible membrane and
- iv) a specific biological agent from
 - c) nucleic acid
 - d) protein

Similarly, if applicants elect c), applicants must elect DNA gene that encodes protein that promotes wound healing or DNA gene that encodes protein that promotes tissue;

And if applicants elects d), applicants must elect a protein that promotes wound healing that is growth factor, or protein that promotes tissue vascularization that is a growth factor.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 25 and 60 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of **all claims readable** thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. A telephone call was not made to applicants to request an oral election to the above restriction requirement because of the complexity of the restriction/election.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

